STATE OF NORTH DAKOTA	IN DISTRICT COURT
COUNTY OF BURLEIGH	SOUTH CENTRAL JUDICIAL DISTRICT
STATE OF NORTH DAKOTA EX REL. WAYNE STENEHJEM, ATTORNEY GENERAL, Plaintiff, -vs- PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY INC.; and DOES I THROUGH 100, INCLUSIVE, Defendants.	Civil No. _____ COMPLAINT CPAT 160247.004

1. Plaintiff, the Attorney General of the State of North Dakota (hereinafter "North Dakota" or "the State"), brings this action against Defendants Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., and Does I through 100, Inclusive (hereinafter "Defendants" or "Purdue") for violating North Dakota Century Code (N.D.C.C.) § 51-15-01 *et seq.*, *Unlawful Sales or Advertising Practices* ("Consumer Fraud Law"), N.D.C.C. § 42-01-01 *et seq. Nuisances* and § 42-02-01 *et seq.*, *Abatement of Common Nuisances*, and common law, and upon information and belief alleges as follows:

I. INTRODUCTION

2. Misuse and overdose of opioids has become a serious public health problem in North Dakota, and opioid addiction and overdoses are having a devastating

impact on North Dakota families, businesses and communities.

3. Purdue manufactures, markets, and sells prescription opioids (hereinafter "opioids"), including brand-name drugs like OxyContin, Butrans, and Hysingla ER, as well as generic opioids.

4. Purdue is not a typical pharmaceutical company. Practically speaking, Purdue has no other product line than opioids. Purdue is one of the nation's largest opioid manufacturers, and pioneered the expansion of the opioid market that created and caused the opioid epidemic in North Dakota. Purdue did this through a massive deceptive marketing scheme designed to convince prescribers and the public that its opioids are effective for treating chronic pain and have a low risk of addiction, contrary to evidence.

5. Purdue's prescription opioids are not typical pharmaceutical products. Opioids are powerful narcotic painkillers. They are highly addictive drugs found in the opium poppy plant, and prescription opioids are synthetic or semi-synthetic drugs derived therefrom. Long acting prescription opioids, including OxyContin and Hysingla ER, are Schedule II narcotics because they have a high potential for abuse and may lead to severe psychological or physical dependence. Prescription opioids are no less addictive than heroin. No other medication routinely used for a nonfatal condition kills patients so frequently.[1]

6. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines and arthritis[2] and, therefore, were

[1] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).
[2] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

used only to treat short-term acute pain or for palliative (end-of-life) care.

7. However, by the late 1990s, Purdue began an aggressive and successful marketing campaign designed to persuade prescribers and patients that opioids can and should be used for chronic pain. The promotion of this scheme relied on intentional deception and misrepresentations regarding the safety and the efficacy of prescription opioids. Through its marketing campaigns, Purdue falsely claimed that opioids could be prescribed and used as a first-line and long-term treatment for patients with chronic pain without a material risk of addiction, and spread other deceptive messages regarding the risks and benefits of opioids. The falsity of Purdue's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain,* issued in 2016 and approved by the FDA ("2016 CDC Guideline").

8. Purdue spent an extraordinary amount of money promoting its opioids. In 2001 alone, Purdue spent a staggering $200 million on marketing for its flagship drug OxyContin.

9. Purdue's marketing efforts were hugely successful. Sales of opioid prescriptions in the U.S. nearly quadrupled from 1999 to 2010. Upon information and belief, Purdue has made an estimated $35 billion selling opioids since 1995. After Purdue introduced OxyContin, sales grew from $48 million in 1996 to almost $1.1 billion in 2000. By 2002 sales reached the $1.5 billion mark, and that same year 259 million prescriptions were written for opioids, which is more than enough to give every American adult their own bottle of pills. In 2010, Purdue generated $3.1 billion dollars off sales of OxyContin.

In 2012, OxyContin represented about 30% of the overall painkiller market. Opioids are now the most prescribed class of drugs, generating $11 billion in revenue for drug companies in 2014.

10. Purdue is continuing its pervasive and deceptive marketing scheme. Facing a shrinking market due to rising criticism, Purdue has not given up the search for new users. In August 2015, over objections from critics, the company received FDA approval to market OxyContin to children as young as eleven years old.

11. Purdue's conduct resulted in a drug epidemic of mass proportions. This epidemic, fueled by opioids lawfully prescribed, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). When those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids illegally, or even to buy heroin.

12. U.S. health care providers wrote 259 million prescriptions for painkillers in 2012, enough for every American adult to have a bottle of pills. In North Dakota, 542,096 opioid prescriptions were reported dispensed in 2014. Three years later, in 2017, the numbers of prescriptions dropped some, but were still high at 438,546 opioid prescriptions. From 2013 through 2017 physicians in North Dakota prescribed supplies of opioids that totaled more than 38 million days of supply.

13. North Dakota's opioid problem resulted in a growing number of unintentional overdose deaths and hospitalizations, a population of addicts who seek drugs from prescribers, a secondary criminal market well stocked by a pipeline of drugs that are diverted to supply addicts who cannot get a prescription, the emergence of the

use of heroin, and a foreseeable financial burden on North Dakota.

14. Purdue's deceptive marketing campaign deprived North Dakota consumers and prescribers of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death, decisions to be made based not on science, but on hype. Purdue deprived consumers, their physicians, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

15. Purdue's conduct has resulted in a financial burden on the State of North Dakota. The North Dakota Department of Human Services, the state agency responsible for administering the State's Medicaid program ("the State's Medicaid program"), has spent millions of dollars on opioid prescriptions for chronic pain and addiction treatment-costs directly attributable to the opioids Purdue unleashed on the State.

16. Purdue's deceptive marketing of opioids and the resulting opioid epidemic also has caused the State to incur additional cost for law enforcement, North Dakota Workforce Safety and Insurance, Department of Correction, North Dakota Department of Human Services, North Dakota Behavioral Health and other agencies.

17. Defendants have engaged in violations of the Consumer Fraud Law, and their conduct has created a public nuisance. To address and punish these violations of law, the State seeks a declaration that Defendants' conduct has violated North Dakota law, an order requiring Defendants to cease their unlawful promotion of opioids and correct their deceptive and unconscionable practices, and an order requiring Defendants to abate the public nuisance they knew their actions would create and, in fact, have created. The State seeks injunctive relief, disgorgement and restitution for amounts the

State's Medicaid program and other state agencies have paid for excessive opioid prescriptions. Further, the State seeks restitution for North Dakota consumers who, like the State, paid for excessive prescriptions of opioids for chronic pain. The State also seeks civil penalties and attorneys' fees and costs, in addition to any other equitable relief authorized by law.

II. JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction over this matter pursuant to N.D.C.C. § 51-15-01 *et seq.*, § 42-01-01 *et seq.*, § 42-02-01 *et seq.*, and common law.

19. Based on information and belief, Defendants may lack a physical presence in North Dakota but are subject to the personal jurisdiction of the North Dakota courts under Rule 4 of the North Dakota Rules of Civil Procedure. N.D.R.Civ.P Rule 4 (2) specifically extends the personal jurisdiction of the North Dakota courts to parties "transacting any business in this state," "contracting to supply or supplying service, goods, or other things in this state," or "committing a tort within or outside this state causing injury to another person or property within this state," when parties have such contact with this state that the exercise of personal jurisdiction over the person does not offend against traditional notions of justice or fair play or the due process of law." N.D.R.Civ. P Rule 4 (2).

20. This Court has personal jurisdiction over Defendants under N.D.R.Civ.P Rule 4 (2) as, at all times relevant to this complaint, they conduct or have conducted business in North Dakota, purposefully direct or directed their actions toward North Dakota, and/or have the requisite minimum contacts with North Dakota necessary to constitutionally permit the Court to exercise jurisdiction.

21. The venue of this action in Burleigh County is proper under N.D.C.C. § 28-04-03 because all or part of the cause of action arose in Burleigh County.

III. PARTIES

A. Plaintiff

22. Plaintiff is the State of North Dakota. The Attorney General is authorized to commence this action pursuant to N.D.C.C. chapters 54-12 and 51-15. The Attorney General is charged, *inter alia*, with the enforcement of Consumer Fraud Law, N.D.C.C. § 51-15-01 *et seq*. Pursuant to N.D.C.C. § 51-15-07, the Attorney General may initiate civil law enforcement proceedings in the name of the State to stop violations of the Consumer Fraud Law or other provisions of law, and to secure such equitable, monetary and other relief as may be appropriate in each case. The Attorney General and the Attorney General's assistants are authorized to institute and prosecute all cases in which the state is a party, whenever in their judgment it would be for the best interests of the state so to do. N.D.C.C. §54-12-02. The Attorney General also is authorized to bring this action pursuant to the common law and *parens patriae* authority to bring an action when it is required for the general welfare of its people. See e.g. State v. Hooker, 87 N.W.2d 337, 340 (N.D.1957).

B. Defendants

23. Defendant PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware, with its principal place of business at 1 Stamford Forum, Stamford, Connecticut 06901-3516. The registered agent for PURDUE PHARMA L.P. is Corporation Service Company, 1709 N 19th Street Ste 3, Bismarck, North Dakota 58501-2121. Defendant PURDUE PHARMA INC. is a New York corporation with its principal

place of business at 1 Stamford Forum, Stamford, Connecticut 06901-3516. PURDUE PHARMA INC. is the General Partner of PURDUE PHARMA L.P. The registered gent for PURDUE PHARMA INC. is Corporation Service Company, 1709 N 19th Street Ste 3, Bismarck, North Dakota 58501-2121. Defendant THE PURDUE FREDERICK COMPANY INC. is a New York Corporation a principal place of business at 1 Stamford Forum, Stamford, Connecticut 06901-3516. THE PURDUE FREDERICK COMPANY INC. does not maintain a registered agent within the State of North Dakota. These Defendants are collectively referred to as "Defendants" or "Purdue."

24. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and North Dakota. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). Purdue has been a leading force in the prescription opioid market both nationwide and in North Dakota.

25. The State lacks information sufficient to identify specifically the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. Therefore, they are sued herein by fictitious names pursuant to N.D.R.Civ.P. Rule 15(c) and the State will amend this Complaint to show their true names and capacities if and when they are ascertained. The State is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

26. Whenever a reference is made in this Complaint to any act of Defendants, that allegation shall mean that each Defendant acted individually and jointly with the other Defendants.

27. At all relevant times, each Defendant committed the acts, caused or directed others to commit the acts, ratified the acts, or permitted others to commit the acts alleged in this Complaint. Additionally, some or all of the Defendants acted as the agent of the other Defendants, and all of the Defendants acted within the scope of their agency if acting as an agent of another.

IV. FACTUAL ALLEGATIONS

28. Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. Due to the lack of evidence that opioids improved patients' abilities to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, physicians generally did not prescribe opioids for chronic pain.

29. Purdue launched OxyContin in 1996. Until then, the company's biggest drug was MS Contin, which had limited appeal, partly because it contained morphine. The new OxyContin had broader appeal because it contained a synthetic version of morphine called oxycodone, which, among other things, carried less social stigma. OxyContin was the first extended release opioid prescription drug. Subsequently, Purdue has launched other extended release or long acting opioids including Butrans, Hysingla

ER, Ryzolt, and Targiniq.

30. To take advantage of the lucrative market for chronic pain patients, and create sustained revenue, Purdue developed a marketing scheme based on deception. Purdue used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use. These false and deceptive statements benefited not only Purdue and the third parties who gained legitimacy when Purdue repeated those statements, but also other opioid manufacturers. Yet these statements were not only unsupported by or contrary to the scientific evidence, they also were contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. Purdue also targeted susceptible prescribers and vulnerable patient populations. Purdue's multi-billion dollar pain franchise, built on deception, depends on continuing to mislead prescribers and patients, and Purdue deployed a deliberate strategy to do so.

A. Purdue Used Multiple Avenues To Disseminate Its False And Deceptive Statements About Opioids.

31. Purdue marketed opioids through multiple avenues, including: (1) direct marketing in form of advertising campaigns touting the purported benefits of its branded drugs and promotion of the use of opioids for chronic pain through "detailers;" (2) marketing through unbranded advertising; (3) speaking through doctors who became known as "key opinion leaders" or "KOLs"; and (4) entering into arrangements with patient and professional organizations to promote opioids for the treatment of chronic pain.

1) Purdue spread and continues to spread its false and deceptive statements through direct marketing of its branded opioids,

32. Purdue's direct marketing of opioids generally proceeded on two tracks. Purdue conducted advertising campaigns touting the purported benefits of its branded drugs and Purdue promoted the use of opioids for chronic pain through "detailers" and small-group speaker programs.

33. Purdue conducted and continues to conduct advertising campaigns pushing the purported benefits of its branded drugs. Upon information and belief, Purdue spent $8.3 million just on medical journal advertising of opioids in 2011.

34. A number of Purdue's branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Purdue, in 2012, ran a series of ads called "Pain vignettes" for OxyContin in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Purdue agreed in 2015 to halt these misleading representations in New York, but they may continue to disseminate them in North Dakota.

35. Purdue paid for direct advertising to physicians in medical journals and distributed videos, making false claims about the benefits of opioids for chronic pain and the risk of addiction. Some of Purdue's misrepresentations made it into the scientific literature and continued to be cited long after publication, causing long-term impact.

36. Purdue promoted the use of opioids for chronic pain through small-group speaker programs. On information and belief, Purdue identified and paid doctors to serve on its speakers' bureaus and to attend programs with speakers and meals paid for by

Purdue. These speaker programs provided:

a. an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug);

b. recognition and compensation for the doctors selected as speakers; and

c. an opportunity to promote the drug through the speaker to his or her peers.

From 1996 to 2001, Purdue held more than 40 national "pain management symposia" at attractive locations hosting more than 5,000 physicians, pharmacists, and nurses who attended these speaker conferences, to promote its new star drug OxyContin.

37. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they, in fact, were presenting a script prepared by Purdue. The presentations conveyed misleading information, omitted material information, and failed to correct Purdue's prior misrepresentations about the risks and benefits of opioids.

38. By July 2002, Purdue also targeted physicians with "educational" programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants.

39. Purdue promoted the use of opioids for chronic pain through "detailers." Detailers are sales representatives who visited individual physicians and medical staff in their offices. Through its detailers, Purdue also offered a patient starter-coupon program for OxyContin that provided patients with a free limited-time prescription for a 7- to 30-day supply.

40. Purdue's detailing to prescribers is effective and Purdue knows its detailing to prescribers is effective.

41. Upon information and belief, Purdue employed the same marketing plans and strategies and deployed the same messages in North Dakota as it did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Purdue's messages are delivered accurately and consistently across marketing channels, including detailing visits, speaker events, and advertising, and in each sales territory. Purdue considers this high level of coordination and uniformity crucial to successfully marketing its drugs.

42. Purdue ensures marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons; the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks; sales training materials; and nationally coordinated advertising.

2) Purdue used unbranded advertising through seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.

43. Purdue deceptively marketed opioids in North Dakota through unbranded advertising, which is advertising that promotes opioid use in general without naming a specific opioid, ostensibly created and disseminated by independent third parties.

44. Purdue controlled the deceptive messages disseminated by seemingly independent third parties by funding, directing, reviewing, editing, and distributing its unbranded advertising. Purdue acted in concert with these third parties to falsely and misleadingly promote opioids for the treatment of chronic pain.

45. Purdue controlled the distribution of these unbranded advertising messages in scientific publications, treatment guidelines, Continuing Medical Education (CME), and medical conferences and seminars, the same way Purdue controlled the distribution of its "core messages" via its own detailers and speaker programs. To this end, Purdue used

third-party public relations firms to help control those messages when they originated from third parties.

46. Purdue marketed through third party, unbranded advertising to avoid regulatory scrutiny because such advertising is not submitted to and typically is not reviewed by the FDA.

47. Purdue also used third party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source.

48. Upon information and belief, Purdue's deceptive unbranded marketing often contradicted what it said in its branded materials reviewed by the FDA.

3) Purdue used Key Opinion Leaders ("KOLs") to influence prescribers.

49. As part of its direct marketing, Purdue also spoke through a small circle of doctors. Upon information and belief, these doctors were selected, funded, and elevated by Purdue because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

50. Purdue paid KOLs to serve as consultants or on its advisory boards and to give talks or present CMEs, and Purdue's support helped these KOLs become respected industry experts. These KOLs touted the benefits of opioids to treat chronic pain, repaying Purdue by advancing its marketing goals. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy.

51. Purdue created opportunities for KOLs to participate in research studies Purdue suggested or chose, and then cited and promoted favorable studies or articles by its KOLs. By contrast, Purdue did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy. Purdue and their KOLs

identified, funded, published, and disseminated research that was designed to assist Purdue's marketing efforts and skew or misrepresent scientific evidence.

52. Purdue's KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid consumer advocacy groups and professional societies that develop, select, and present CMEs. Purdue was able to direct and exert control over each of these activities through its KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

53. Purdue's use of KOLs provides the false appearance of unbiased and reliable support for the use of opioids for chronic pain.

4) Purdue promoted its opioids through Front Groups.

54. Purdue also entered into arrangements with seemingly unbiased and independent patient and professional organizations ("Front Groups") to promote opioids for the treatment of chronic pain.

55. Under the direction and control of Purdue, these Front Groups generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy.

56. The Front Groups assisted Purdue by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Purdue.

57. The Front Groups depended on Purdue for funding, and Purdue exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. Despite this, the Front Groups held themselves out as independent and serving the needs of their members, whether their members were patients suffering from pain or doctors treating and

prescribing to those patients. Some of the KOLs used by Purdue also served on the boards of these front groups.

58. Purdue utilized many Front Groups, including American Pain Foundation ("APF"), the American Pain Society ("APS"), and the American Academy of Pain Medicine ("AAPM").

59. The Front Groups helped Purdue spread its deceptive messages about the risks and benefits of long-term opioid therapy. For example, in 2011 APF, over which Purdue exercised control, published "*A Policymaker's Guide to Understanding Pain & Its Management,*" which represented that pain had been "undertreated" due to "[m]isconceptions about opioid addiction," and perpetuated the concept of pseudoaddiction.

B. Purdue's Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.

60. When Purdue first launched OxyContin and sought to broaden the opioid market, Purdue found that physicians were too worried about the risk of addiction. Purdue deliberately set out to change prescriber's attitude about opioids. To convince prescribers and patients in North Dakota that opioids can and should be used to treat chronic pain, Purdue had to convince them that long-term opioid use is both safe and helpful. Knowing that it could do so only by deceiving those prescribers and patients about the risks and benefits of long-term opioid use, Purdue made claims not supported by, or contrary to, scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that scientific evidence confirmed that Purdue's claims were false and deceptive, Purdue continues to spread them even today.

61. Purdue's false representations include claims that: (1) pain patients do not become addicted to opioids; (2) extended release opioids are steady-state and less addictive, (3) physicians can identify and manage the risk of addiction; (4) patients who

appear to be addicted are merely pseudoaddicted and should be treated with more opioids; (5) addiction is not a product of the drug, rather a product of patients and prescribers; and (6) abuse and addiction is manifested in misuse of opioids, such as injection and snorting, not by oral use.

62. Purdue sought to deceive prescribers and patients by omitting and failing to adequately disclose the risk of addiction and other health effects and by failing to correct past misrepresentations regarding the risk of addiction.

63. To convince prescribers and patients that opioids are safe, Purdue deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, and misrepresented the benefits of opioids for long-term opioid use, through a series of claims that conclusively have been debunked by the FDA and CDC. These claims, described below, reinforced each other and created dangerously misleading impressions.

64. The numerous and longstanding misrepresentations of the risks of long-term opioid use spread by Purdue successfully convinced prescribers and patients to discount those risks.

1) Purdue misrepresented and omitted the risks of addiction.

65. Purdue falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly, and failed to disclose the greater risk of addiction with prolonged use of opioids.

66. Through misrepresentations and omissions, Purdue sought to convince prescribers that while opioids are generally addictive, patients with legitimate pain under the physician's care would not become addicted.

67. Purdue variously represented, through websites and publications, that opioids posed a low risk of addiction, and that addiction was limited to those who obtained opioids through some sort of illicit means. For example, Purdue sponsored APF's

Treatment Options: A Guide for People Living with Pain (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. Further, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management,* which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." Additionally, upon information and belief, detailers for Purdue in North Dakota minimized, trivialized, or omitted any discussion with prescribers of the risk of addiction, and routinely did not correct misconceptions about addiction created by the misrepresentations noted above.

68. Purdue's claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]...)." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

69. According to the CDC, the prevalence of opioid dependence may be as high as 26% among patients in primary care receiving opioids from chronic pain.[3] An estimated 8-12% of people who are prescribed opioids develop an opioid addiction, and the percentage increases significantly for long-term users of opioids.

70. The FDA further exposed the falsity of Purdue's claims about the low risk of addiction when it announced changes to the labels for Extended Release/Long Acting (ER/LA) opioids in 2013 and for Immediate Release (IR) opioids in 2016. In its

[3] CDC guideline for prescribing opioids for chronic pain — United States, 2016. MMWR Recomm Rep 2016;65(RR-1):1-49; See https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

71. Long-term opioid use is associated with addiction, misuse and mortality, and the greatest risk with long-term opioid use is the risk of fatal overdose. Long-term use of opioids is exceptionally dangerous because patients develop tolerance and loss of effectiveness to the drug over time, requiring higher doses to achieve effect. At higher doses, opioids can cause respiratory depression, due to their pharmacological effect on the part of the brain that regulates breathing. Respiratory depression can cause the user to stop breathing, which leads to death by overdose.

72. The risk of addiction, misuse and overdose increases with the duration of use. Patients can quickly become dependent on opioids which often will cause the patient to experience psychologically and physically agonizing withdrawal symptoms, which may last for weeks, making it very hard for the patient to discontinue the use even after a relatively short time-period of initial use. For many patients that have used opioids long-term, the primary benefit of opioid therapy is "not going into withdrawal." Physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days. Experts have noted that more than a few days of exposure to opioids significantly increases hazards and that each day of unnecessary opioid use increases likelihood of physical dependence. A CDC study from 2017 shows

that the sharpest increases in the likelihood of long-term use came at five days after the initial prescription, with another spike seen at one month. This mix of tolerance, dependence and addiction is what makes long-term use of opioids so lethal.

73. Long-term use of opioids correlates with many negative health consequences, including hyperalgesia, sleep-related breathing problems, digestive issues, cardiovascular issues, hormonal or endocrine dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased fall and fracture risk, depression, neonatal abstinence syndrome, and potential dangerous or fatal interaction with alcohol and other medications, and is also associated with other types of addiction. A study published in the *Pharmacoepidemiology & Drug Safety* (*PDS*) found a higher risk of alcohol abuse and heroin use among people who had been prescribed opioids for long periods.

74. Purdue, on the other hand, attributes the addiction, abuse and overdose problem to the patients, not the opioids. Purdue has even represented that "bad apple" patients were the source of addiction, and not the opioids themselves. Contrary to Purdue's representations, addiction is the result of opioid use, not misuse or abuse.

75. The warnings on Purdue's own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

76. Since Purdue's began its aggressive marketing of opioids for long-term use, the long-term use of prescription opioids has increased significantly. According to a study published in the *Pharmacoepidemiology & Drug Safety* (*PDS*) 79.4 of percent of opioid users in 2013-2014 were long-term users compared with 45.1 percent in 1999-2000. In 1999-2000, 4.1 percent of adults were taking prescription opioid medications, and from 2013-2014, 6.8 percent of US adults were taking prescription opioids. The increase

mostly was driven by an increase in the long-term use of prescription opioids, which increased from 1.8 percent of adults to 5.4 percent.

2) Purdue falsely promoted the phenomenon "pseudoaddiction."

77. Purdue falsely instructed prescribers and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Purdue called this phenomenon "pseudoaddiction" and described it as an accepted scientific concept.

78. The term "pseudoaddiction" was invented by Dr. David Haddox, who later went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Purdue. The term was meant to differentiate between "undertreated pain" and "true addiction."

79. Purdue deceptively described "pseudoaddiction" as an accepted scientific concept, although the concept was not substantiated by competent scientific evidence.

80. Through publications and CMEs, Purdue variously represented that patient behaviors, including demanding certain opioids by name, manipulative behavior to get opioids, hoarding of opioids, seeing more than one physician to secure opioids (also known as "Doctor Shopping"), or taking significantly more of an opioid than is prescribed, even in a patient with a history of drug abuse, was "pseudoaddiction." For example, Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, which deceptively promoted the concept of "pseudoaddiction," by explaining that "[p]atients with unrelieved pain may become focused on obtaining medications and may otherwise seem inappropriately 'drug seeking,' which may be misidentified as addiction by the patient's physician." In addition, Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

81. Through publications and CMEs Purdue went on to advocate that such a

'drug seeking' condition was a sign that the patient's pain was being under-treated, and that the patient should be prescribed higher doses, and longer acting versions of the opioids. For example, the 2007 Purdue-sponsored book *Responsible Opioid Prescribing* explains that pseudoaddiction is resolved when the patient receives adequate analgesia, and in order to tell whether a patient is addicted to opioids, physicians are to give the patient more opioids and then see if he keeps engaging in "demanding or manipulative behavior" after his demands are met or the manipulation has achieved its desired result.

82. Purdue's efforts to promote "pseudoaddiction" intended to convince North Dakota opioid prescribers to ignore signs that their patients were addicted.

83. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer- term use," and that physicians should " reassess pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

84. In 2012 Purdue KOL Dr. Lynn Webster acknowledged that pseudoaddiction "obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a concept." Even pain specialists such as KOL Russell Portenoy, who helped popularized the term, has acknowledged that the concept of pseudoaddiction in chronic pain was not supported by evidence. Purdue promoted pseudoaddiction through at least 2013, and has failed to correct past misrepresentations.

3) Purdue falsely represented that addiction risk mitigation tools could prevent addiction.

85. Purdue deceptively claimed that screening patients would effectively manage addiction risk and prevent addiction. Purdue falsely instructed prescribers and patients that addiction risk mitigation tools, such as screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. For example, Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between prescribers and patients can "ensure that you take the opioid as prescribed."

86. These misrepresentations of mitigation tools as a means to manage addiction risk and prevent addiction were especially insidious because Purdue aimed them at general practitioners and family physicians, including nurse practitioners and physician assistants. Purdue's misrepresentations made these physicians feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain, by making them believe addiction is avoidable and a result of noncompliant patients.

87. Through publications, webinars, and scientific conferences, Purdue represented that patients at a high risk of addiction could still receive opioid treatment for chronic pain as long as there was a properly structured approach to this treatment. For example, in 2011 Purdue sponsored a webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

88. Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies, such as screening tools, patient contracts, urine

drug testing, or pill counts widely believed by doctors to detect and deter abuse, "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the 2016 CDC Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that prescribers "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

89. Purdue's unsubstantiated and deceptive statements about prescribers' ability to manage risk of addiction and prevent abuse were made with the intent to influence prescribers and induce prescription of opioids, and were essential to Purdue's marketing strategy.

4) Purdue misrepresented that opioid withdrawals could be addressed by tapering.

90. Purdue falsely claimed that opioid dependence easily can be addressed by tapering and that opioid withdrawal is not a problem. Purdue failed to disclose or grossly understated the difficulty of tapering, particularly after long-term opioid use. Purdue downplayed the difficult and painful effects that many patients experience when dosages are lowered or opioids discontinued, which decrease the likelihood that those patients will be able to taper or stop taking opioids.

91. Purdue made these claims to underplay the risk and impact of addiction and make prescribers feel more comfortable starting patients on opioids. For example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardship that often accompany cessation of use, even gradual tapering off.

92. Purdue deceptively minimized the significant symptoms of opioid

withdrawal which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction.

93. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The 2016 CDC Guideline further states: "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence." The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

5) Purdue encouraged escalating dosages and failed to disclose the greater risks at higher dosages

94. Purdue falsely claimed that physicians and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks of addiction and overdose at higher dosages. The ability to escalate dosages was a critical message in the efforts to market opioids for long-term use to treat chronic pain because, absent the ability to do so, physicians would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Purdue wanted to make sure physicians maintained patients on the opioids.

95. Purdue offered seven different tablet strengths of OxyContin, and the seven dosing strengths and the resulting ability to adjust or "titrate" the dosage was an important focus of Purdue's marketing of OxyContin. Purdue's sales representatives highlighted the seven tablet strengths as an advantage of OxyContin and claimed that it gave

prescribers flexibility in titrating dosages and the ability to titrate slowly, while omitting to disclose the increased risk associated with higher dosages.

96. Through websites, CMEs and publications, Purdue variously represented that there was "no ceiling dose," and that dosages could be increased without limit. One publication even claimed that dosage limitations were "disadvantages" of other pain medications. Purdue's *In the Face of Pain* website suggested that if a patient's physician did not prescribe what was, in the patient's view, a sufficient dosage of opioids then that patient should find a new physician. Purdue also sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.

97. These claims conflict with the scientific evidence, which shows that overdose risk increases in a dose-response manner, as confirmed by the FDA and CDC. As explained in the 2016 CDC Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that the clinical evidence "found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent" and that there is an "increased risk for opioid use disorder, respiratory depression, and death at higher dosages." The CDC advises physicians to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

98. Numbers from the State Medicaid Program indicate that approximately 43% of all OxyContin tablets prescribed and paid for through Medicaid between 2007 and 2017 were 40 mg or higher. The conversion factor between one milligram of oxycodone and the morphine milligram equivalent (MME) is 1.5. Therefore, 40mg of OxyContin twice a

day equals 120 MMEs in a day, which is above what the daily 90 MMEs the CDC advises.

99. According to the CDC, one study showed that one in 550 patients died from opioid-related overdose at a median of 2.6 years from their first opioid prescription, and that one in 32 patients who escalated to opioid dosages >200 morphine milligram equivalents (MME) died from opioid-related overdose.

100. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. Upon information and belief, the FDA acknowledged that available data do suggest a relationship between increased opioid dose and risk of certain adverse events, in 2013, and further noted that studies appear to credibly suggest a positive association between high dose opioid use and the risk of overdose and/or overdose mortality.

6) Purdue deceptively marketed its abuse-deterrent opioids as safer.

101. Purdue has made misleading claims about the ability of its so-called abuse-deterrent opioid formulations to deter abuse. Purdue's deceptive marketing of its abuse-deterrent opioids has created false impressions that these opioids can curb addiction and abuse.

102. Purdue's 2010 reformulation of OxyContin instituted what Purdue calls "abuse deterrent" formulations of its extended release opioids. The extended release opioids are very large doses of opioids placed in a time-released matrix designed to release the drug over time. If this time-release formulation can be defeated, then the user can get the concentrated dose all at once. In addition, by dissolving the drug, the user can inject it directly into the bloodstream to receive a high. The abuse deterrent formulations (AD opioids) are designed to be harder to crush, chew, or grind, or become gelatinous when combined with a liquid, making them harder to snort or inject.

103. Purdue's marketing of the reformulated abuse deterrent opioids misled and deceived physicians to write prescriptions for AD opioids with the mistaken belief that they were safer. It allowed physicians to discount evidence of abuse and addiction to other

non-AD opioids. The development of the AD opioids also allowed Purdue to avoid competition from generic versions of OxyContin, which were denied when OxyContin was removed from the market as unsafe when the patent was set to expire in 2013, thus maintaining its price, sales and profits. Purdue's marketing of AD opioids changed physicians' perception and their willingness to continue prescribing opioids.

104. However, abuse deterrent opioids are not "impossible to abuse."[4] They can be defeated, often quickly and easily, by those who are determined to do so. Most importantly, they do not stop oral intake, the most common avenue for opioid misuse and abuse. In fact, there is no evidence that orally administered opioids are less addictive. The CDC has observed that abuse deterrent technologies do not prevent overdose through oral intake. Abuse deterrent opioids still can be and are widely abused by people who become addicted by swallowing the pills, just as the bottle instructs. Further, abuse deterrent formulations do not reduce the rate of misuse and abuse by patients who become addicted after long-term use or who escalate their use by taking more pills or higher doses. Since the introduction of the abuse deterrent opioids, there is little or no data suggesting it had a meaningful reduction in abuse. Moreover, despite the introduction of abuse deterrent opioids in 2010, opioid deaths have continued to increase.

105. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading,

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[4] FDA Facts: Abuse-Deterrent Opioid Medications, available at: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm600788.htm (last visited May 8, 2018).

and/or insufficiently proven do not serve the public health."[5]

106. Purdue was the first opioid manufacturer to create an FDA-approved abuse deterrence formula, and this has featured prominently in Purdue's marketing of its drugs. Purdue used abuse deterrence to distinguish its drugs. Purdue's unlawful marketing has successfully sought to associate abuse deterrent formulas with safety. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[6]

7) Purdue grossly overstated the benefits of chronic opioid therapy and falsely represented that opioid use improved patients' function and quality of life.

107. To convince prescribers and patients that opioids should be used to treat chronic pain, Purdue also had to persuade them that there was a significant upside to long-term opioid use.

108. For example, Purdue falsely claimed that long-term opioid use improved patients' function and quality of life. Through advertisements, publications, guides, and sales representatives, Purdue represented that relief of pain by opioids improved patient functions, that opioids give pain patients a quality of life they deserve, and that "multiple clinical studies" had shown that opioids were effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.

109. Purdue sales representatives claimed that its extended release opioids would benefit patients' sleep, function and pain control, and that moving a patient to extended release opioids would help patients with life interruptions, including sleep interruptions by pain and work interruption for taking pills.

110. These claims are unsubstantiated and find no support in the scientific

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[5] Id.

[6] Catherine S. Hwang, et al., Prescription Drug Abuse: A National Survey of Primary Care Physicians, 175(2) JAMA INTERN, MED, 302-4 (Dec. 8, 2014).

literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline concluded: "there is no good evidence that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely." (Emphasis added.)

111. The 2016 CDC Guideline states that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[7] Despite this, Purdue falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

112. The CDC has also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life. The few longer-term studies of opioid use had consistently poor results and several studies have shown that opioids for chronic pain may actually worsen pain and functioning. A 2012 study in the *Journal of Pain*, which followed 69,000 women over three years, found that patients who received opioid treatment were less likely to have improvement in pain, and had worsened function. A 2017 study by Alan Krueger, a Princeton University economist, suggests that opioids may be the cause of as much as a 20 percent decline in workforce participation among prime age men, and as much as 25 percent of the workforce participation decline

[7] FDA's September 2013 letter to Andrew Kolodny, MD, President of PROP, from Janet Woodcock, MD, Director Center for Drug Evaluation and Research; See http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf

for women.[8]

8) Purdue provided deceptive comparisons between the risks and benefits of opioids and those of alternative forms of pain treatment.

113. Purdue's marketing presented a misleading comparison between the risks and benefits of opioids and other pain treatment methods by influencing and controlling marketing materials that falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs. These practices have the capacity to deceive prescribers and patients who would then look to and favor opioids over other therapies such as acetaminophen or NSAIDs for the treatment of chronic pain. For example, Purdue sponsored *Treatment Options: A Guide for People Living with Pain (2007)*, which attributed an exaggerated number of deaths to NSAIDs overdoses and warned that risks for NSAIDs increase if "taken more than a period of months," while omitting any corresponding warning about the long-term risk of opioids. While opioid prescribing increased between 2000 and 2010, the prescribing of non-opioid medications for pain decreased.

114. Purdue's claims were not supported by competent scientific evidence. Once again, Purdue's representations contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for whom alternative treatment options" like non-opioid drugs "are inadequate."

9) Purdue deceptively claimed OxyContin was effective for 12 hours.

115. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not

[8] Alan B. Krueger, Princeton University, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Economic Activity, BPEA Conference Drafts, September 7-8, 2017, available at https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf.

last for 12 hours, a fact that Purdue has known at all times relevant to this action. Purdue sought the 12-hour dosing frequency despite knowing it does not last 12 hours in many patients in order to maintain a competitive advantage. What made OxyContin stand out from other opioid-based prescription painkillers was the claim of longer-lasting pain relief through what it called "controlled release."

116. The 12-hour dosing allowed Purdue to advertise OxyContin as an around the clock pain reliever. A 1996 news release from Purdue Pharma stated "unlike short-acting pain-relievers, which must be taken every three to six hours — often on an 'as needed basis' — OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night. Dosing with OxyContin Tablets on a regular schedule spares patients from anxious 'clock-watching' when pain must be controlled over long periods of time."[9] When patients complained the drug did not last for 12 hours, Purdue's sales representatives encouraged North Dakota physicians to increase or "titrate" the dosage rather than frequency in order to stick with the 12-hour interval, causing physicians to prescribe higher dose opioids.

117. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which the release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008, in response to a Citizen petition by the Connecticut Attorney General, that a "substantial proportion of chronic pain patients" taking OxyContin experience it.[10] This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more

[9] http://www.news-herald.com/general-news/20170216/how-aggressive-tactics-by-the-makers-of-oxycontin-helped-create-a-crisis (last visited May 8, 2018).
[10] http://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf.

dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

C. Purdue Targeted Susceptible Prescribers and Vulnerable Patient Populations.

118. As a part of its deceptive marketing scheme, Purdue identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including North Dakota.

119. Purdue, as an example, focused a lot of its deceptive marketing on primary care physicians, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to have received specialized education about treating pain and the risks and benefits of opioids and therefore more likely to accept and rely on Purdue's misrepresentations.

120. Purdue also targeted vulnerable patient populations, like the elderly and veterans, who tend to suffer from chronic pain.

121. Medicare Part D covered OxyContin very well, and Purdue's sales representatives heavily pushed OxyContin for patients over the age of 65 by pointing out the easy access to the drug through Medicare Part D. Purdue made prescribers more comfortable in prescribing opioids to the elderly by highlighting the numbers of patients over 65 in the clinical trials. Purdue misrepresented or overstated the benefits, side effects and safety concerns of OxyContin in the geriatric population, and omitted the fact that the product label states that respiratory depression is a particular concern in elderly patients. Purdue sales representatives particularly promoted use of OxyContin for elderly patients with moderate persistent pain who take painkillers every day, and made false or deceptive comparative claims between its opioids and other competing medications.

122. Additionally, Purdue's sales representatives encouraged use of Butrans in nursing homes, omitting the fact that the label for Butrans requires caution when administering Butrans in elderly patients because of increased risk of respiratory depression.[11]

123. Purdue targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of harm, and increased vulnerability to adverse drug effects and interactions. The 2016 CDC Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that prescribers use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

124. In an effort to reach veterans, Purdue sponsored APF's *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families,* published in 2009. APF intended *Exit Wounds* to be a guide to pain management for veterans and their family members.[12] It misrepresents the risks and benefits of opioids and omits warnings about potentially fatal interactions between opioids and anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder - the target audience for *Exit Wounds.* Purdue's website www.inthefaceofpain.com held *Exit Wounds out as a* resource for veterans seeking pain relief.

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[11] https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf (Last viewed May 9, 2018).

[12] American Pain Foundation, Annual Report, *Advancing Pain Management* (2009), available at https://www.guidestar.org/ViewEdoc.aspx?eDocId=1063988&approved=True (last viewed May 9, 2018).

D. Although Purdue Knew That Its Marketing Of Opioids Was False And Deceptive, Purdue Fraudulently Concealed Its Misconduct.

125. Purdue made, promoted, and profited from the misrepresentations about the risks and benefits of opioids for chronic pain even though it knew that its misrepresentations were false and deceptive.

126. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. Purdue knew this, and had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths - all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Purdue's misrepresentations.

127. Moreover, at all times relevant to this Complaint, Purdue took steps to avoid detection of, and to fraudulently conceal, its deceptive marketing and unlawful, unconscionable and fraudulent conduct.

128. Purdue disguised its own role in the deceptive marketing of opioids by funding and working through third parties like Front Groups and KOLs. Purdue never disclosed its role in shaping, editing, and approving the content of information and materials disseminated by these third parties.

129. Purdue exerted considerable influence on promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public.

130. Finally, Purdue manipulated its promotional materials and the scientific literature to make it falsely appear that these items were accurate, truthful, and supported

by objective evidence when they were not.

131. The lack of support for Purdue's deceptive messages was not apparent to physicians who would rely upon them in making treatment decisions, nor could it have been detected by the State.

132. Purdue successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of Purdue's industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

E. By Increasing Opioid Prescriptions And Use, Purdue's Deceptive Marketing Scheme Has Fueled The Opioid Epidemic.

133. Purdue's misrepresentations deceived prescribers and patients about the risks and benefits of long-term opioid use. Studies reveal that many prescribers and patients are not aware of or do not understand these risks and benefits. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[13]

134. Purdue's marketing scheme caused and continues to cause physicians in North Dakota to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014.[14] Absent Purdue's deceptive marketing scheme, these prescribers would not have prescribed as many opioids.

135. Purdue's marketing scheme also caused and continues to cause patients

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[13] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), *available at* http://www.hazeldenbettyford.org/about-us/news-media/press-release/2016-doctors-missing-questions-that-could-prevent-opioid-addiction (last visited May 8, 2018).

[14] https://www.cdc.gov/drugoverdose/data/prescribing.html (last visited May 8, 2018)

to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Purdue's deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

136. The escalating number of opioid prescriptions written by prescribers who were deceived by Purdue's deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and North Dakota.

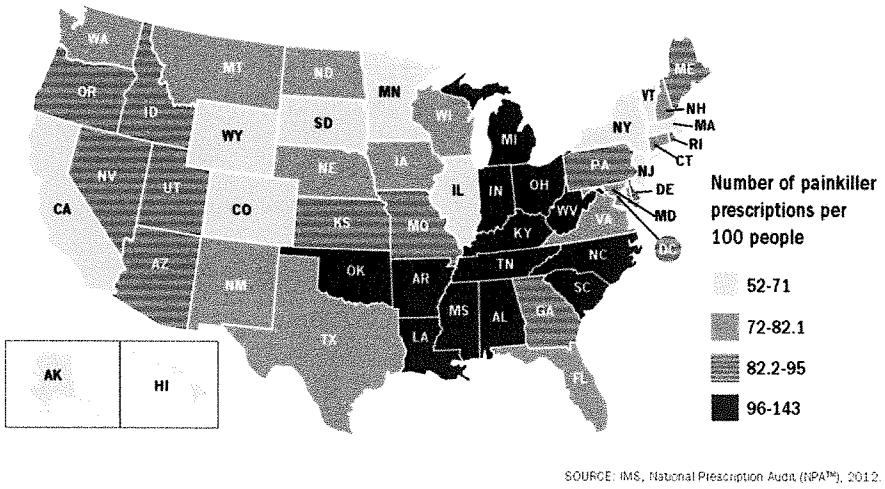
137. In 2013, a couple of years after the peak of overall opioid sales, more than 7.65 million daily doses of prescription opioids were dispensed in North Dakota, enough for a 10 and ½ days' supply for every woman, man and child in the state. As recently as last year, more than 6.8 million daily doses of prescription opioids were reported, enough for 9 days' supply for every woman, man and child in the state.

Opioid Prescriptions for ND					
Year	**Days Supply**	**Prescriptions Count**	**Quantity**	**Population**	**Days Supply per population**
2013	7,650,899	533,998	31,222,936.27	722,908	10.6
2014	7,914,394	542,096	31,462,254.82	738,658	10.7
2015	8,138,757	539,199	31,496,516.19	754,859	10.8
2016	7,546,343	484,226	28,139,419.53	755,548	10
2017	6,803,640	438,546	24,656,304.72	755,393	9

Source: ND Board of Pharmacy, and United States Census Bureau

138. In 2012, North Dakota physicians wrote 75 painkiller prescriptions per 100 people in North Dakota.[15]

[15] 2016 ND Epidemiological Profile, https://prevention.nd.gov/sites/default/files/pdf/EPI%20Profile%202016.pdf



SOURCE: IMS, National Prescription Audit (NPA™), 2012.

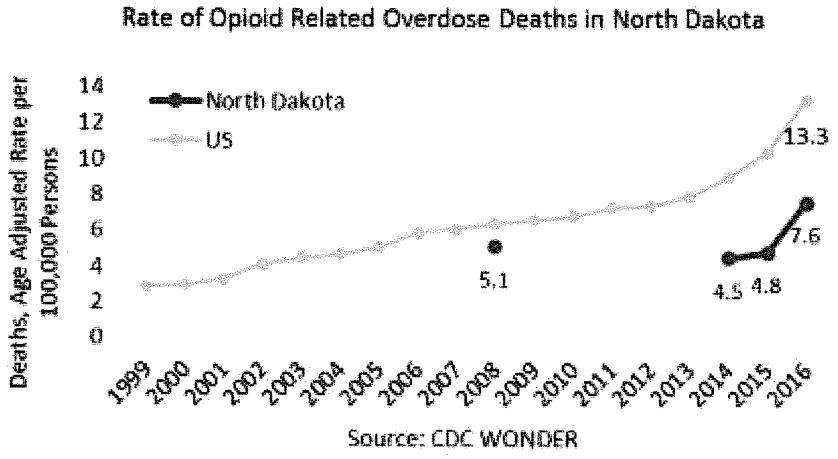
139. Since 2011, sales of opioids have decreased some, due to what a physician's advocate described as a "cultural change" in response to rising concerns over the opioid epidemic. In 2015, North Dakota providers wrote approximately 539,000 opioid prescriptions, which represents 71 opioid prescriptions per 100 persons, and in 2017 with 439,000 opioid prescriptions, the number was down to 58 opioid prescriptions per 100 persons.

140. The greatest risk with long-term opioid use is the risk of fatal overdose. Drug overdose is the leading cause of accidental death in America. As of 2016, opioid overdoses killed more people than firearm accidents and motor vehicle accidents. Oxycodone (such as OxyContin) and Hydrocodone (such as Hysingla ER) are the two types of prescription painkillers most likely to be associated with fatal overdose. In 2014, more than six out of ten drug overdose deaths in the United States involved an opioid (28,000 deaths) and nearly half of those deaths were from prescription opioids.[16] There were 54 drug overdose deaths in North Dakota in 2016, a rate of 7.6 deaths per 100,000 people.[17] Although this is below the national average, the sudden rise from 31 deaths in

[16] https://prevention.nd.gov/sites/default/files/pdf/DataBook2017.pdf, citing Center for Disease Control (CDC), 2000-2014

[17] National Institute for Drug Abuse, North Dakota Opioid Summary, see https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/north-dakota-opioid-summary (last visited May 8, 2018)

2014 is troubling. Even more concerning is the fact that the number of opioid overdose deaths in North Dakota have increased 390% since 2013 when the number of opioid overdose deaths in North Dakota was 11. In 2016, almost 39% (21 out of 54) of all opioid overdose deaths were from prescription opioids.



141. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained: "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with overdoses involving the most commonly used opioid pain relievers."[18]

142. Contrary to Purdue's representations, most opioid addiction begins with legitimately *prescribed* opioids, and, therefore, could have been prevented had Purdue's representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet.[19] In 2014, a study showed that 65.9% of North Dakota persons who

[18] *See Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report,* Vol. 64, Nos. 50 & 51 (January I, 2016), which can be found at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w (last visited May8, 2018).

[19] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012), available at https://www.samhsa.gov/data/sites/default/files/Revised2k11NSDUHSummNatFindings/Revised2k11NSDUHSummNatFindings/NSDUHresults2011.htm (last visited May 8, 2018)

abused prescription pain relievers obtained them from a friend or relative.[20]

143. Purdue's deceptive marketing scheme also has had a significant detrimental impact on children in North Dakota in a number of ways. The number of youth who reported prescription drug abuse increased from 2% in 2007 to 6% in 2011.[21] The overprescribing of opioids has given young children access to opioids, through opioids prescribed to friends or relatives in the same household or to the children themselves.[22] In 2009, 15% of high school students reported they had taken a prescription drug without a doctor's prescription.[23] In 2011, 16% of North Dakota high school students reported they had abused prescription drugs.[24] The number stays fairly consistent in 2015 when 14.5% of high school student reports that they had used prescription drugs without a prescription one or more times during their lifetime. Prescription drugs also reach middle school children, with 6% of middle school students had taken a prescription drug without a doctor's prescription in 2009. A survey done by the North Dakota State Epidemiological Outcomes Workgroup (SEOW) reveals that of the North Dakota college students who in 2014 had used prescription drugs non-medically in the past year, 63% stated that they did so for the first time before turning 18.

144. The Child Welfare League of America reports that in 2014, approximately 1,000 children ages 12 to 17 in North Dakota needed but had not received treatment for illicit drug use in the past year.[25]

145. The overprescribing of opioids has made prescription opioids much easier to access. There is a great number of unused medications in people's medicine cabinets, which contributes to the high statistic of people that first get addicted after obtaining

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[20] https://prevention.nd.gov/sites/default/files/pdf/PrescriptionDrugs.pdf
[21] https://prevention.nd.gov/sites/default/files/pdf/prescription-drug-data-brief.pdf
[22] https://prevention.nd.gov/sites/default/files/pdf/PrescriptionDrugs.pdf
[23] https://prevention.nd.gov/sites/default/files/pdf/2009-2011-state-data-booklt.pdf
[24] https://prevention.nd.gov/sites/default/files/pdf/prescription-drug-data-brief.pdf
[25] *See* North Dakota's Children 2017, available at: https://www.cwla.org/wp-content/uploads/2017/04/NORTH-DAKOTA-revised-1.pdf

opioids free from a friend or relative. In 2015, approximately 1 in 4 (or 23.8%) North Dakota adults perceived it is not at all difficult for adults or youths to access prescription drugs in their community. As of April 27, 2018, more than 11 tons, or 22,612 pounds, of unwanted and unused medications have been collected from the "Take Back" containers at local law enforcement agencies in North Dakota. [26]

146. Even infants have been affected by opioid abuse and over-prescription. There has been a dramatic increase in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (NAS), which can occur in an infant exposed *in utero* to addictive, illegal or prescription drugs. According to the National Institutes of Health (NIH), 21,732 babies were born with neonatal abstinence syndrome (NAS) in the United States in 2012. Not only is this a large number in itself, especially considering it most likely underreports the issue, it also represents a 500 percent increase since 2000.[27] In 2015, Senate Bill 2367 created a task force on substance exposed newborns. The Task Force reported that

> The North Dakota Department of Human Services provided the following data from state Medicaid claims. Approximately 120 babies born in fiscal year 2013 were diagnosed with NAS. The average cost to North Dakota Medicaid for the first year of life for a baby born with NAS is approximately $19,300, compared to $8,200 for a baby born without NAS. Using the difference of the average costs, children diagnosed with NAS incurred medical expenses estimated to cost North Dakota Medicaid at least $1,332,000 in fiscal year 2013. Considering the impacts of underdiagnosing, increasing opioid addiction rates and increasing hospital costs, that figure has likely risen significantly since 2013.
>
> Almost 6 percent of women who are admitted to treatment programs for substance abuse in North Dakota are pregnant.

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[26] Sydney Mook, Forum News Service, Bismarck Tribune (December 28, 2017), available at http://bismarcktribune.com/news/state-and-regional/north-dakota-looks-to-reduce-number-of-opioid-addictions-overdoses/article_7e9fd594-aca9-5336-a735-24e634be3afa.html (last visited May 8, 2018).
[27] Report to Legislative Management FINAL REPORT June 17, 2016 https://www.ndcourts.gov/court/committees/tribstat/Final%20ReportSubExposedNewbornsTaskForce.pdf

> One insurer in North Dakota reviewed their claims data to help determine the incidence of NAS in North Dakota. They identified ten babies diagnosed with NAS during their neonatal period in 2014 and 2015. Those babies' neonatal hospital charges amounted to more than $1,055,000. Since most babies with NAS are not diagnosed with the syndrome, these data most likely underreport the incidence and cost of NAS to insurers in our state.[28]

147. NAS babies are more likely to have respiratory problems and low birth weights, contributing to an average neonatal hospital stay of 16.9 days for them compared to 2.1 days for babies without NAS. According to the NIH, the lengthy neonatal hospital stays for babies with NAS in 2012 alone cost approximately $1.5 billion, with more than 80 percent of those costs (more than $1.2 billion) borne by Medicaid, funded jointly by federal and state governments. The National Association of State and Territorial Health Officials estimates that Medicaid covers 78 percent of babies born with NAS. Medicaid incurs extra health care costs for each baby born with NAS throughout his or her childhood. Longitudinal studies have shown children exposed to drugs *in utero* can have lasting physical, neurodevelopmental, speech and behavioral problems including irritability, aggression, depression and others. Medicaid programs, state health and social services agencies and school systems often provide the bulk of services to address these problems.

148. The foster care system also has observed children affected by opioid use. The North Dakota Department of Human Services reported a parent's drug abuse as the number one reason for children age 0-17 entering foster care in 2014, 2015 and 2016. The number of children placed in foster care with parental drug abuse as entry reason increased 16% percent between January 2014 and December 2016.

149. The State has incurred tremendous health care costs associated with opioid

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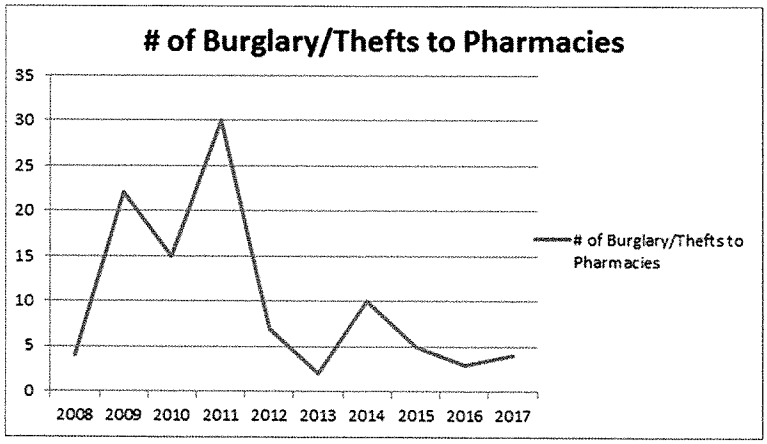
[28] Id.

abuse. The Child Welfare League of America also reports that in 2015, health care costs related to opioid abuse in North Dakota reached $33 million. [29]

150. The State has also incurred other costs due to criminal activity resulting from the increased prescription and use of opioid. Purdue's success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury.

151. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, such as: doctor shopping, forged prescriptions, falsified pharmacy records, or employees who steal from their place of employment. The opioid epidemic has promoted a growing trend of crimes against pharmacies. The North Dakota Board of Pharmacy reports that, in 2011 alone, 30 burglaries or thefts were committed or attempted against North Dakota pharmacies, compared to 4 in 2008. Since 2011, the number has decreased. However, between 2008 through 2017, 102 burglaries or thefts were committed or attempted against North Dakota pharmacies.



Source: North Dakota Board of Pharmacy

[29] *See* North Dakota's Children 2017, available at: https://www.cwla.org/wp-content/uploads/2017/04/NORTH-DAKOTA-revised-1.pdf

152. The number of drug cases submitted to the State Crime Laboratory increased by 26% from 2013 to 2015. The number of incidents involving narcotics (other than hashish, marijuana, cocaine, crack cocaine, heroin, morphine or opium) increased 43% during the same time period, and drug cases involving heroin increased by more than 400%.[30] In the past five years, heroin related drug violations have skyrocketed, with an increase from 4 cases in 2010 to 177 cases in 2015, a 4,300% increase. According to Bismarck Police Department, heroin seizures have dramatically increased and there are daily overdoses that are vastly underreported.

153. The rise in opioid addiction caused by Purdue's marketing scheme has resulted in an explosion in heroin use, including in North Dakota. According to the National Institute on Drug Abuse, on a national basis, nearly 80% of those who used heroin had previously used prescription opioids.[31] People who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin.[32] According to the American Society of Addiction Medicine, four in five new heroin users started out by misusing prescription painkillers, and 94 percent of opioid-addicted patients said that they switched to heroin because prescription opioids were more expensive and harder to obtain.[33] With the North Dakota oil boom, the state's population increased. This led to an increase in the demand for drugs and resulted in an escalation of the price of black market prescription narcotics. Drug addicts began to seek alternatives, increasingly turning to heroin.[34] A Bismarck police department detective stated to the local news station KFYR in November of 2017: "[t]he number [of opioid overdoses] keeps rising and I think it has

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[30] https://attorneygeneral.nd.gov/sites/ag/files/documents/Comprehensive-Status-and-Trends-Report.pdf

[31] *See* https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (last visited May 8, 2018).

[32] https://prevention.nd.gov/sites/default/files/pdf/DataBook2017.pdf, citing National Survey on Drug Use and Health (NSDUH) National Findings, 2011-2013.

[33] https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf

[34] https://attorneygeneral.nd.gov/sites/ag/files/documents/Comprehensive-Status-and-Trends-Report.pdf

to do with the availability that we have of heroin and opioids within our town."[35] In Bismarck, there were ten opioid overdoses between October 27, 2017 and November 20, 2017, and Narcan had been administered over 16 times. The Bismarck Detective further stated that: "[o]pioids, it's a completely different animal, it could be anybody." "[P]robably one of the most important things we're dealing with law enforcement right now is the opioid epidemic," the Detective added.

154. More than 2 million Americans are addicted to opioid painkillers or heroin, but only 1 in 5 is receiving treatment for their disorder, according to the Substance Abuse and Mental Health Services Administration. There is a growing need for treatment for opioid abuse. For example, a few years ago two out of every 10 people seeking group treatment in Dickinson for drug abuse was dealing with an opioid addiction. In 2017, the number had risen to nearly seven out of 10.[36] In 2013, a North Dakota treatment provider stated: "[W]e receive on average 50 calls per week requesting opioid treatment services."[37]

155. The number of people in substance abuse treatment reporting prescription drug abuse is increasing.[38] The three Opioid Treatment Programs in the state have had over 515 admissions since August 2016. The percentage of North Dakota adults reporting Schedule II drug use when admitted to substance abuse treatment at the North Dakota Regional Human Service Centers increased from 28% to 53% between 2011 and 2017. During the same time, the numbers of North Dakota youth reporting Schedule II drug use when admitted to substance abuse treatment has increased from 6% to 14%.

156. The percentage of adult individuals specifically reporting use of opiates,

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[35] Daniela Hurtado, Bismarck Tribune article "Opioid Overdoses on the rise", see http://www.kfyrtv.com/content/news/Opioid-Overdoses-on-the-Rise-458811223.html (last visited May 8, 2018).

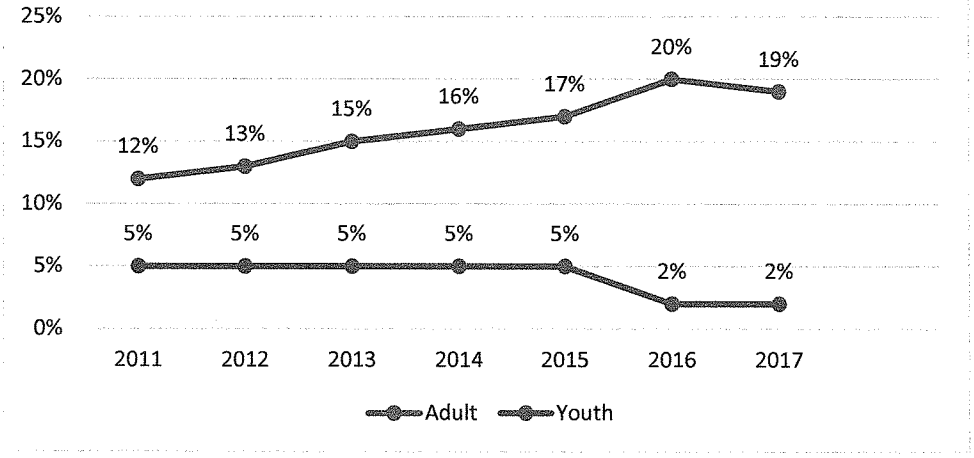
[36] http://bismarcktribune.com/news/state-and-regional/as-opioid-use-rises-across-north-dakota-officials-say-treatment/article_6610037f-486b-585f-8fcc-d1f233cb0655.html (last visited May 8, 2018)

[37] https://prevention.nd.gov/sites/default/files/pdf/2013-substance-use-data-booklet.pdf

[38] https://prevention.nd.gov/sites/default/files/pdf/prescription-drug-data-brief.pdf

including prescription opioids, such as oxycodone and hydrocodone, other opiates, heroin, or hydromorphone, when admitted to substance abuse treatment at the Regional Human Service Centers, increased from 12% to 19% between 2011 and 2017. The percentage of youth reporting use of opiates remained at 5% between 2011 and 2015, and decreased to 2% in 2016 and 2017.

Figure: Percentage of individuals reporting Opioid use when admitted to substance abuse treatment at Regional Human Service Centers, CYs 2011-2017



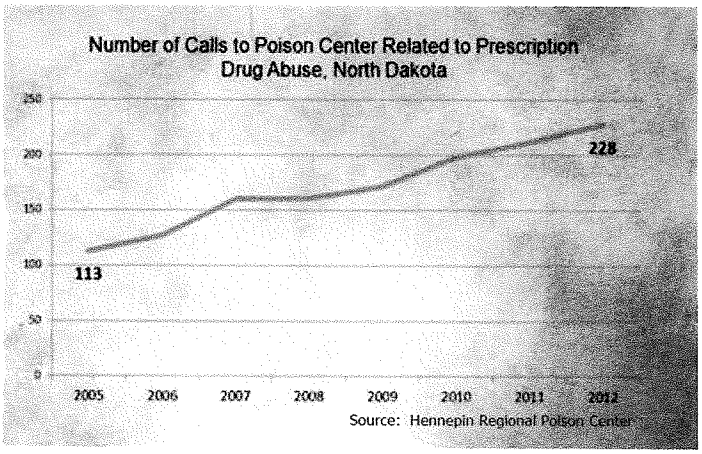
Data Source: Department of Human Services, Behavioral Health Division

157. The Medical Director of a North Dakota private non-profit alcohol/drug treatment and education program stated to KFYR television in November 2017 that they have had an increase of patients addicted to opioids in the last several years. She stated that "[i]t is deadly, it is scary, and we're seeing people come in because of these rash of overdoses that we've had. We've seen people come in and they're scared. They're afraid for their lives." She further stated that people get addicted for many reasons, like pain.[39] The non-profit is treating their opioid addicted patients with medicine like Suboxone. "The reason we started using medication to treat opioid dependence ... is people couldn't get

[39]KFYR TV (November 20, 2017) "Opioid overdoses on the rise", see http://www.kfyrtv.com/content/news/Opioid-Overdoses-on-the-Rise-458811223.html (last visited May 8, 2018)

through the withdrawal, couldn't engage in treatment," said the Medical Director.

158. The number of calls to poison center related to prescription drug abuse more than doubled between 2005 and 2012:



159. The North Dakota Prescription Drug Monitoring Program (NDPDMP) is a tool that gives a physician the ability to look up a patient's controlled substances/drugs of concern history, coordinate care, receive patient alerts, perform patient searches, and view the physicians own prescribing history. The North Dakota Board of Medicine has issued guidelines for use of the NDPDMP by prescribers of controlled substances, which guidelines provide that when the physician has knowledge that the patient exhibits any of the certain signs of potential abuse or diversion, the physician shall request a report from the Prescription Drug Monitoring Program. In third quarter of 2015, licensed addiction counselors submitted 1,081 requests to the NDPDMP, up from 851 in the fourth quarter of 2014. In the same quarter, law enforcement submitted 89 requests to the NDPDMP.

160. Purdue knew or should have known about the harm that its marketing scheme has caused. Purdue closely monitored its sales and the habits of prescribers. Their sales representatives, who visited prescribers and attended CMEs, knew which prescribers were receiving their messages and how they were responding. Purdue also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Purdue knew - and, indeed,

intended-that its misrepresentations would persuade physicians to prescribe, and patients to use, its opioids for chronic pain.

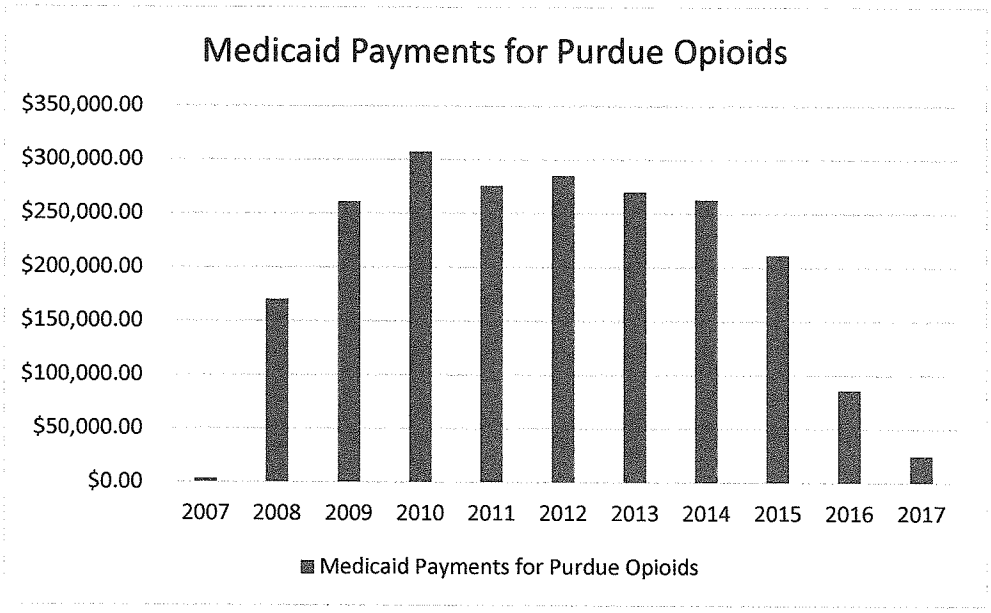
161. Purdue's actions are not permitted, nor excused, by the fact that its drug labels may have allowed, or did not exclude, the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Purdue license to misrepresent the risks and benefits of opioids.

F. Purdue's' Unlawful Opioid Promotion Scheme Has Caused Substantial Economic Injury To the State and State Agencies

162. Through the actions described in the paragraphs above, including false statements, representations, and omissions, Purdue caused substantial economic injury to the State far beyond overdose mortality rate. The State spends significant public resources on medical services, law enforcement, corrections, workers' compensation, diversion programs, prosecution, probation, treatment, and child welfare.

163. Through the actions described in the paragraphs above, including false statements and representations, Purdue caused substantial economic injury to State agencies in form of: (1) claims for payment to be made to the State's Medicaid program and other state agencies; and (2) growing costs associated with the treatment of patients addicted to prescription opioids.

164. Between 2007 and 2017, the State's Medicaid program paid out more than $11 million in narcotics pharmacy payments, which includes more than $2.1 million in payments for opioids manufactured by Purdue. Many of those claims were submitted and paid based on Purdue's false statements and representations. Since 2007 more than 6,600 prescriptions have been submitted to the State's Medicaid program for Purdue's opioids, together prescribing more than 350,000 pills.



Source: ND Department of Human Services

165. There have been growing costs associated with the treatment of patients addicted to prescription opioids. Since 2000, the North Dakota Department of Human Services has spent $46,530 on Medication Assisted Treatments ("MATs"), which utilize drugs designed to treat opiate addiction. This amount is in addition to funds reimbursed through the SUD Voucher Program and received from federal discretionary grant funding. As the number of addicted patients increase, more funds will be used by the Department of Human Services for MATs.

166. In addition to the cost incurred to the State's Medicaid program Purdue's deceptive marketing of opioids has also caused the State to incur additional costs for law enforcement, North Dakota Workforce Safety and Insurance, Department of Correction, North Dakota Department of Human Services, North Dakota Behavioral Health, and other State agencies.

167. Purdue's' conduct has caused significant harm to the State, its residents and its communities, including lives lost, addiction endured, the creation of an illicit drug market and all its concomitant crime and costs, unrealized economic productivity, and broken families and homes.

G. Purdue's Fraudulent Marketing Has Led To Record Profits.

168. While the use of opioids has taken a toll on North Dakota and its residents, Purdue has realized substantial profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Purdue, and are expected to continue generating that same level of revenues. Upon information and belief, Purdue has generated estimated sales of more than $35 billion since 1995, with annual revenues around $3 billion, mostly from OxyContin.

H. Purdue is Responsible for the Opioid Crisis

169. The impacts of opioids on the State and North Dakota residents are inextricably linked with Purdue's marketing campaign designed to convince prescribers, patients, and the public that opioids were an effective medical solution for chronic pain.

170. Because of Purdue's efforts, opioid use has grown to epidemic proportions and the death rates continue to rise while Purdue continues to market and sell drugs that it knows are deadly.

171. The Attorney General asks the court to stop Purdue's deceptive marketing and order such equitable remedies necessary to begin addressing the opioid epidemic, including injective relief, abatement of nuisance, disgorgement, restitution, civil penalties and attorney fees and costs.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
NORTH DAKOTA CONSUMER FAUD LAW
DECEPTIVE PRACTICES
N.D.C.C. §51-15-01, *ET SEQ.*

172. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

173. Purdue, in the course of engaging in the marketing, promotion, selling, and distributing of opioids, has engaged in deceptive acts or practices, fraud, false pretense, false promise, or misrepresentation, made with the intent that others rely thereon, in connection with the sale or advertisement of merchandise, in violation of North Dakota's Consumer Fraud Law, N.D.C.C. §51-15-02 *et seq.*

174. Purdue engaged in deceptive acts or practices and made or disseminated false, deceptive or misleading statements, by, among other things:

a. Creating, sponsoring, and assisting in the distribution of advertisements, marketing materials or patient educational materials to North Dakota consumers that contained misrepresentations, or deceptive, false or misleading statements;

b. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

c. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic pain;

d. Providing financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning

the use of opioids to treat chronic pain;

e. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic pain;

f. Directly distributing or assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic pain;

g. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic pain and misrepresented the risk of addiction;

h. Making deceptive statements concerning the use of opioids to treat chronic pain to North Dakota prescribers through in-person detailing.

i. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites sponsored or operated by Purdue;

j. Misrepresenting, directly or indirectly, or sponsoring, endorsing, directly distributing, or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks, benefits, safety or effectiveness of opioids versus NSAIDs or other painkillers;

k. Misrepresenting, directly or indirectly, that addiction mitigation or screening tools are effective to manage addiction risk and prevent addiction;

l. Misrepresenting, directly or indirectly, that OxyContin had "no ceiling dose," and that dosages could be increased without limit, and failing to disclose the increased risks and side effects at higher dosages;

m. Creating and disseminating advertisements that contained deceptive or unsubstantiated claims concerning the ability of opioids to improve function

long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic pain;

n. Developing and disseminating "scientific studies' that deceptively concluded opioids are safe and effective for the long-term treatment of chronic pain and that opioids improve quality of life, while concealing contrary data;

o. Promoting OxyContin as providing a full 12 hour of pain relief, and failing to disclose that it does not for a majority of patients;

p. Promoting the reformulated abuse deterrent opioids in a misleading manner to created false impressions that these opioids can curb addiction and abuse;

q. Misrepresenting, directly or indirectly, the safety of its opioids when taken by the elderly, and failing to disclose the increased risk in geriatric patients; and

r. Distributing brochures to prescribers, patients, and law enforcement officials that include deceptive statements concerning the indicators of possible opioid abuse.

175. As alleged herein, Purdue, at all times relevant to this Complaint, violated the Consumer Fraud Law by making deceptive representations about the use of opioids to treat chronic pain. Purdue *also* omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids.

176. In addition to failing to adequately disclose the risk of addiction, abuse, overdose, and respiratory depression, Purdue also deceptively omitted and failed to disclose other significant health risks from long-term opioid use, such as hyperalgesia, sleep-related breathing problems, digestive issues, cardiovascular issues, hormonal or endocrine dysfunction, decline in immune function, mental clouding, confusion, dizziness,

increased fall and fracture risk, depression, neonatal abstinence syndrome, and potential dangerous or fatal interaction with alcohol and other medications.

177. Purdue's omissions rendered even its seemingly truthful statements about opioids deceptive.

178. Purdue's deceptive representations and omissions were calculated to deceive physicians, the State and its residents and induce the prescription of, purchase of and payment for opioids.

179. Purdue made the false or deceptive statements or representations and omitted material facts with the intent that others rely thereon.

180. Purdue made the false or deceptive statements or representations and omitted material facts with the intent of inducing North Dakota physicians to prescribe and the State's Medicaid program and other state agencies to pay for opioids for long-term treatment of chronic pain.

181. Purdue's conduct caused prescribers to write prescriptions for opioids to treat chronic pain that were paid for by patients, the State's Medicaid program, and other state agencies.

182. Purdue is responsible for the claims submitted and the amount the State's Medicaid program and other state agencies spent on its opioids.

183. Purdue made the false or deceptive statements or representations and omitted material facts with the intent of inducing North Dakota physicians to prescribe opioids when they otherwise would not have, and patients to request and obtain opioids when they otherwise would not have.

184. Purdue knew or should have known that its representations were false and otherwise unsupported by valid or sufficient medical or scientific studies, and omitted material information that would have prevented the State, state agencies, and North Dakota persons from paying for opioid prescriptions for chronic pain.

185. Because of Purdue's deceptive acts or practices, the State of North Dakota, State agencies, and North Dakota persons are entitled to relief in an amount to be determined at trial.

186. Purdue engaged in violations of North Dakota's Consumer Fraud Law, N.D.C.C. § 51-15-02, by engaging in deceptive acts or practices, for which the court:

a. May order injunctive relief as provided in N.D.C.C. § 51-15-07;

b. May order Defendants to pay to the State of North Dakota a civil penalty of up to $5,000 for each violation as provided in N.D.C.C. § 51-15-11;

c. Shall order Defendants to pay to the State of North Dakota the costs, expenses, and attorney's fees incurred by the Attorney General in the investigation and prosecution of this action as provided in N.D.C.C. § 51-15-10; and

d. May order such relief as may be necessary to prevent the use or employment of deceptive acts or practices by Defendants or to restore any loss suffered by persons as a result of the deceptive acts or practices of Defendants as provided in N.D.C.C. § 51-15-07.

187. The Sate alleges that each false statement, misrepresentation or omission made by Purdue in connection with the sale or advertisement of opioids is a separate and actionable violation of N.D.C.C. § 51-15-02, for purposes of awarding penalties pursuant N.D.C.C §51-15-11.

SECOND CAUSE OF ACTION
NORTH DAKOTA CONSUMER FAUD LAW
UNCONSCIONABLE PRACRICES
N.D.C.C. §51-15-01, *ET SEQ.*

188. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

189. Purdue, in the course of engaging in the marketing, promotion, selling, and

distributing opioids, has engaged in the act, use, or employment of acts or practices, in connection with the sale or advertisement of any merchandise, which are unconscionable or which caused or are likely to cause substantial injury to a person which is not reasonably avoidable by the injured person and not outweighed by countervailing benefits to consumers or to competition in violation of North Dakota's Consumer Fraud Law, N.D.C.C. §51-15-02, by, among other things:

a. Marketing and selling opioids for long-term use in treating chronic pain without sufficient evidence of efficacy, while also understating the risk of addiction and the ease with which addiction could be treated;

b. Influencing physicians' prescription decisions for particular patients in sales calls for which the patients were not present;

c. Encouraging physicians to ignore or reject regulatory guidance, thereby undermining public policy;

d. Encouraging physicians to prescribe opioids as a first-line treatment for chronic pain in conflict with professional standards, CDC Guidelines and public policy;

e. Targeting the elderly or veterans; and

f. Targeting and encouraging physicians with high rates of opioid prescription, seeking to cause high volume prescribers to continue prescribing at those rates and encouraging additional prescriptions.

190. Purdue's acts or practices were unconscionable in that they caused, or are likely to cause, substantial injury to North Dakota persons and the State, in form of addiction, abuse, overdose, death and economic loss.

191. The injury to the State and its residents is not outweighed by any countervailing benefits to consumers or competition. Consumers' interests in knowing the true facts regarding merchandise offered for purchase, particularly medications they are

taking and purchasing at substantial cost, negate any purported benefits to consumers. A person has an important interest in being informed of this information in order to make an intelligent and informed decision about whether to purchase and use opioids. There is little social utility to opioid use and any potential value is outweighed by the gravity of the harm inflicted by Purdue's actions.

192. The injury to the State and its residents is not an injury that the injured persons themselves could reasonably have avoided because the State and its residents did not know the true facts regarding the risks and benefits of opioids, and had no reason to believe that Purdue's statements were false, misleading, or omitted material information.

193. Purdue's acts and practices offend established public policy and are immoral, unethical, oppressive, unscrupulous and/or substantially injurious to the State and its residents. Purdue's conduct immorally and unscrupulously deprived prescribers of the information needed to make appropriate decisions whether to prescribe opioids to their patients, and deprived patients of the ability to make informed decisions in important, sometimes life-or-death, matters regarding their health.

194. Purdue's deceptive and unconscionable conduct in the advertising, marketing, distribution, and sale of opioids to physicians and persons in North Dakota injured the State and numerous North Dakota residents. Purdue's deceptive and unconscionable conduct affects the public interest because Purdue created a public health crisis by deceptively marketing and selling opioids to numerous persons in North Dakota. These unlawful practices were part of Purdue's very business model and regular course of business operations and were repeated.

195. Purdue's unconscionable practices caused or are likely to cause physicians to prescribe opioids to treat chronic pain when they otherwise would not have, patients to request and obtain opioids when they otherwise would not have, and patients, the State's

Medicaid program, or other state agencies, to pay for opioids when they otherwise would not have.

196. Because of Purdue's unconscionable conduct, the State of North Dakota, State agencies, and North Dakota persons are entitled to relief in an amount to be determined at trial.

197. Purdue engaged in violations of North Dakota's Consumer Fraud Law, N.D.C.C. § 51-15-02, by engaging in unconscionable acts or practices, for which the court:

a. May order injunctive relief as provided in N.D.C.C. § 51-15-07;

b. May order Defendants to pay to the State of North Dakota a civil penalty of up to $5,000 for each violation as provided in N.D.C.C. § 51-15-11;

c. Shall order Defendants to pay to the State of North Dakota the costs, expenses, and attorney's fees incurred by the Attorney General in the investigation and prosecution of this action as provided in N.D.C.C. § 51-15-10; and

d. May order such relief as may be necessary to prevent the use or employment of deceptive acts or practices by Defendants or to restore any loss suffered by persons as a result of the deceptive acts or practices of Defendants as provided in N.D.C.C. § 51-15-07.

198. The Sate alleges that each sale resulting from the unconscionable practice perpetrated by Purdue is a separate and actionable violation of N.D.C.C. § 51-15-02, for purposes of awarding penalties pursuant N.D.C.C §51-15-11.

THIRD CAUSE OF ACTION
STATUTORY PUBLIC NUISANCE
N.D.C.C. §42-01-01 et seq. and §42-02-01 et seq.

199. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

200. This action is brought by the State under N.D.C.C. §42-02-01 to seek abatement of the public nuisance that Purdue's conduct created or was a substantial factor in creating.

201. Purdue's conduct caused and maintained the overprescribing and sale of opioids for long-term treatment of chronic pain at such volumes and degree as to create an epidemic.

202. Purdue, independently and in concert with others, has created, and/or contributed to creating and maintaining a condition that is harmful to the health of North Dakota residents or interferes with the comfortable enjoyment of life, such that it constitutes a nuisance in violation of North Dakota law; for example:

a. Opioid use, abuse, and overdose deaths have increased throughout the state;

b. The increased rate of prescription of opioids has led to unnecessary opioid abuse, addiction, overdose, injuries and death;

c. Children have been harmed by the easy access to prescription opioids and exposure to opioids prescribed to family members or others, and infants have been born addicted to opioids, causing withdrawals symptoms and lasting developmental impacts.

d. Residents of the state have endured emotional and financial harm from caring for loved ones addicted to or injured by opioids.

e. Employers have lost the value of productive and healthy employees who

suffered from adverse consequences of opioid use, and increases in workers' compensation claims.

f. Overprescribing of opioids have created drugs available for criminal use, and fueled a wave of addiction, abuse, and injury.

g. Demand for prescription opioids has created additional illicit markets in other opiates, particularly heroin. Many users who were initially dependent on prescription opioids and then were unable to obtain or afford prescription opioids turned to heroin[40] as a cheaper alternative, fueling an increase in heroin use.

h. The increase in the number of people who are addicted to or abuse opioids, and the diversion of opioids into the criminal market, have increased the demand on emergency services and law enforcement in the State.

i. Certain locations, including public spaces, have attracted drug dealers and addicts, rendering them and the surrounding private property less safe or unsafe.

j. The greater demand for emergency services, law enforcement, courts, addiction treatment, and social services places an unreasonable burden on State and local resources.

k. Increased health care costs for individuals, families, and the State.

l. A spread of false and misleading information regarding opioids.

m. A distortion of the medical standard of care for treating chronic pain.

203. The condition created by Purdue annoys, injures, or endangers the comfort, repose, health, and safety of the people of North Dakota. The harms created by Purdue

[40] According to Bismarck PD, the current (2018) price of a large prescription pill of opioids (75-80 mg) costs $75-80, compared to "a point" of heroin (1/10th of a gram or 100mg) which costs $40-60.

have taxed the human, medical, public health, law enforcement and financial resources of the State.

204. The condition created by Purdue constitutes a public nuisance because it affects entire communities, neighborhoods and a considerable number of persons in North Dakota. Purdue's conduct has affected and continues to affect a considerable number of people within the State and is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

205. The public nuisance created by Purdue's actions is substantial and unreasonable. The significant harm that was, and continues to be, inflicted to North Dakota communities outweighs any offsetting benefit. There is little social utility to opioid use and any potential value is outweighed by the gravity of the harm inflicted by Purdue's actions.

206. Purdue, by its actions knew or should have known that its promotion of opioid use would create a public nuisance. The public nuisance and associated financial and economic losses were foreseeable to Purdue. Purdue knew or should have known that its massive production of opioids, the expansion of the market and promotion of the expanded use of opioids for pain management, together with misrepresentations of the benefits and adverse effects of opioids, would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

207. Purdue is responsible for the public nuisance to which it has contributed regardless of when its conduct contributed to that nuisance, as "[n]o lapse of time can legalize a public nuisance amounting to an actual obstruction of public right." N.D.C.C. §42-01-14.

208. Purdue's actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Purdue's actions were, at the least, a substantial factor in health care professionals and patients not accurately knowing, assessing and weighing

the risks and benefits of opioids for chronic pain.

209. Purdue is liable for a public nuisance because it acted without express authority of a statute.

210. Without Purdue's actions, the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Purdue's actions have and will continue to injure and harm the State and many residents throughout the state, including patients with chronic pain who take opioids, their families, and their communities at large.

211. The health and safety of the residents of the State, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State and the State's residents. The State and its residents have a right to be free from conduct that endangers their health and safety. Purdue's unlawful marketing and business practices interfered in the enjoyment of this public right by the State and its residents.

212. The public nuisance created, perpetuated, and maintained by Purdue can be abated and further reoccurrence of such harm and inconvenience can be prevented.

213. Purdue created or assisted in the creation of the epidemic of opioid use and injury, and is liable for abating it and remediating the harm created.

VI. PRAYER FOR RELIEF

214. WHEREFORE, Plaintiff respectfully prays:

A. That the acts alleged herein be declared to be unlawful in violation of State law and that the Court enter a judgment declaring them to be so, pursuant to N.D.C.C. §32-23-01 et seq.;

B. That Purdue be ordered to cease any ongoing unlawful promotion of

opioids and correct its past unlawful conduct;

C. That Purdue be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent or omit the risks and benefits of the use of opioids for chronic pain, and from continuing to violate North Dakota law;

D. That Purdue be ordered to abate the public nuisance that Purdue created, pay for the equitable costs of abating this nuisance, and remediate the harm created;

E. That Purdue be ordered to pay restitution to the State, State agencies, including the Department of Human Services, and North Dakota residents, and provide such relief that may be necessary to restore to any person in interest any money, or property that may have been acquired by means of its unlawful practice, and be required to pay all costs of distributing and administrating the same, including the cost of a third-party administrator;

F. That the Court order disgorgement of all the ill-gotten gains obtained by Purdue as a result of its unlawful conduct, which in equity belong to the State and its residents;

G. That Plaintiff receive an award of civil penalties of up to five thousand dollars ($5,000.00) for each and every violation of the Consumer Fraud Law, pursuant to N.D.C.C. §51-15-11;

H. That Purdue be required to pay to Plaintiff any reasonable attorney fees and costs for the prosecution and investigation of this action, as provided by N.D.C.C. § 51-15-10 and § 42-02-09;

I. That Plaintiff recover pre- and post-judgment interest as provided by law; and

J. That the Court order such other and further equitable relief as the Court deems just, necessary, and appropriate.

Respectfully submitted this 15th day of May, 2018

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